

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s)	Savio, Alicia Santos	Examiner:	Hissong, Bruce D.
Serial No.:	10/529,923	Group Art Unit:	1646
Confirmation No.:	5270	Docket:	976-24 PCT/US/RCE II
Filed:	August 29, 2005	Dated:	October 31, 2007
For:	VACCINE COMPOSITION COMPRISING INTERLEUKIN-15 (IL-15)		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**FILED VIA EFS-WEB**

**AMENDMENT**

Sir:

In response to a final office action mailed October 18, 2007, Applicants submit the following amendments and remarks for entry in the above-referenced application. Reconsideration is respectfully requested. A Request for Continued Examination is also being filed concurrently.

**Amendments to the Claims** begin on page 2 of this paper.

**Remarks** begin on page 3 of this paper.

**Listing of the Claims**

This listing of claims will replace all prior versions and listings of claims in the application:

1-21. Cancelled.

22. (Presently Amended) A method for generating a neutralizing antibody response against autologous IL-15 to a human in need thereof, wherein said method comprises administering to ~~a host~~ said human a composition comprising human IL-15 and aluminum hydroxide, wherein the IL-15 is an antigen and wherein said IL-15 antigen generates neutralizing self-antibodies against IL-15.

23. (Currently Amended) The ~~composition~~ method according to claim ~~14~~ 22, wherein the IL-15 antigen is coupled to a carrier protein, and wherein the carrier protein is P64k protein.

### **REMARKS**

Claims 14-17 and 20 are cancelled herein. Claims 22 and 23 have been amended. Support for the amendment to Claim 22 can be found throughout the application, for example, page 4, lines 19-22. Claim 23 has been amended to depend upon Claim 22 instead of Claim 14. Accordingly, Claims 22 and 23 remain pending. In view of the amendments and the remarks herein, reconsideration is respectfully requested.

The examiner objected to Claim 16. Claim 16 has been cancelled thereby making the objection moot.

Claims 16, 17 and 20 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Claims 16, 17 and 20 have been cancelled, thereby making the rejection moot.

Claims 14 and 23 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Claims 12 and 23 were also rejected under §112, second paragraph for being indefinite. The examiner has asserted that the recitation of “native” IL-15 is not adequately described in the specification and is new matter. Claim 23 was rejected for depending from rejected Claim 14.

Claim 14 has been cancelled. Claim 23 has been amended to depend from Claim 22. Accordingly, withdrawal of these rejections is respectfully requested.

Claim 15 stands rejected under 35 U.S.C. §102(b) as being anticipated by Grabstein et al. (WO 95/27722). Claim 15 has been cancelled rendering this rejection moot.

Claims 14-15 and 22-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Grabstein et al. (WO 95/27722), in view of Gonzalez et al. and further in view of Brewer et al. The examiner asserts that Grabstein et al. teaches compositions of IL-15 produced in *E. coli* which would inherently have a different glycosylation pattern than that of autologous IL-15. The examiner further asserts that Gonzalez discloses protein P64k functions as an effective carrier protein when conjugated to weekly immunogenic proteins. The examiner further asserts that Brewer teaches that aluminum hydroxide is an adjuvant

capable of inducing strong antigenic-specific antibody. Therefore, the examiner concludes that one of ordinary skill in the art would be motivated to create a composition comprising IL-15 and aluminum hydroxide. Lastly, the examiner asserts that, because Claim 22 does not specify a host, one of ordinary skill in the art would have the motivation and the ability to administer a composition comprising IL-15 to a host for the purpose of generating neutralizing antibodies against IL-15.

The examiner asserts that the motivation to administer the composition comes from the teachings of Grabstein. However, Grabstein does not teach a method for generating a neutralizing antibody response against autologous IL-15 to generate neutralizing self-antibodies against IL-15. Claim 22 has been amended to further clarify that the host is a human in need of a neutralizing antibody response against autologous IL-15.

Rather, Grabstein et al. discloses that the administration of IL-15 was intended to stimulate T lymphocyte proliferation. The examples in Grabstein show the induction of CTLL-2 proliferation. Accordingly, Grabstein seeks to promote the biological activity of IL-15 as a cytokine.

In contrast, Claim 22 relates to generating a neutralizing response, i.e., generating self-antibodies against IL-15. This neutralizing response would inhibit the activity of IL-15 as a cytokine desired by Grabstein.

Therefore, one skilled in the art reading Grabstein would not administer human IL-15 and aluminum hydroxide to generate neutralizing self-antibodies against IL-15 as set forth in Claim 22. Accordingly, withdrawal of the obviousness rejection is respectfully requested.

Applicants respectfully submit that the application is now in proper form for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of the application, it is respectfully requested that the Examiner contact

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Applicants' attorney at the telephone number provided below.

Respectfully submitted,

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